Northwest Center for Outcomes Research in Older Adults: A VA HSR&D Center of Excellence

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RANDOMIZED TRIAL OF HEARING AMPLIFICATION TECHNOLOGIES

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BACKGROUND

Hearing loss is one of the most common chronic illnesses in the United States, because it affects over 25% of elderly Americans. There is extensive evidence that hearing aids significantly improve quality of life for patients with sensorineural hearing loss (Jerger, Chmiel, Florin, Pirozzolo, & Wilson, 1996).

However, the relative impact of different types of hearing aids, and more specifically, different types of hearing aid features, is unknown. With advances in hearing aid technology resulting in an array of products with varying features and expense, more information about the relative impact of different hearing aids is needed to help clinicians provide informed treatment recommendations. Furthermore, it is important to assess how patients perceive these differences. Therefore, the purpose of this study was to compare the relative effectiveness of two different hearing aids (with different hearing aid technologies) and an assistive listening device against the absence of any form of amplification.

METHODS

Patients. Participants aged 50 or older were recruited from patients seeking care at the audiology clinic at VA Puget Sound, either for diagnostic visits or for hearing aid evaluations. Patients were included if they had symmetric, bilateral sensorineural hearing loss (SNHL). Patients were *excluded* if they had prior hearing aid experience, poor cognitive function as measured by a score of 23 or lower on the mini-mental status examination, and poor manual dexterity. Informed consent was obtained from patients meeting study criteria. Enrollment began on October, 1998, and was completed September, 1999. Patients eligible for VA-issued hearing aids were randomized to receive either the standard non-programmable hearing aid that the Seattle VA routinely dispenses ('standard'), or a programmable aid with a directional microphone ('programmable'). Randomization was performed in blocks of 4, with separate randomization for patients 50-65 and older than 65 to ensure relatively similar age distributions between treatment arms.

Hearing Amplification Devices. All hearing aids were binaural half-shell, in-the-ear analog models. Because we were interested in hearing aid effectiveness in everyday listening environments, we allowed the audiologists to make decisions about the fitting requirements within the bounds of the experimental design. The conventional hearing aid was a non-programmable, omni-directional aid. The program-

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Emblem: "Soul Catcher" ...a Northwest Coast Indian symbol used to ward off spirits that brought physical or mental illness. Artist: Marvin Oliver.

mable hearing aid had a switchable directional microphone and remote control. The assistive listening device was a Pocket-Talker, which consists of a microphone worn in a shirt pocket, connected by a visible wire to headphones or ear buds. In each case, patients received routine instructions on the use, care and function of the amplification devices. All patients were seen for routine clinical follow-up, including counseling and adjustments as needed.

Data Collection. Data were collected with individual interviews and through self-administered questionnaires at baseline before randomization, and then again at 1 and 3 months after receiving the hearing amplification device. In addition to the interviews and self-administered questionnaires, patients were asked to maintain a hearing diary for the duration of the study. Patients recorded the number of hours they used their hearing amplification device each day (when applicable) and hearing-related issues they encountered. Non-hearing aid patients were given their diaries on the day of randomization. Hearing aid patients received their diaries on the day they were fitted with their aids.

'Quality of life' is increasingly common to consider in hearing aid studies. We used a psychometric scale called the Hearing Handicap Inventory in the Elderly (HHIE), a 25-item hearing-specific quality of life scale with two subscales that measure the emotional and social impact of hearing loss (Ventry & Weinstein, 1982). The scale is scored from 0 to 100, with 100 representing the best quality of life. Second, we performed a qualitative ('clinimetric') analysis of open-ended comments from the diaries (Feinstein, 1987).

In addition, we collected adherence data based upon the number of hours that subjects recorded they used their amplification device each day. Finally, we collected willingness-to-pay data. Willingness-to-pay is an economic construct popularized by health services researchers. It measures how much patients value a particular treatment (or health state). In its simplest form, patients are literally asked how much they would be willing to pay to have a treatment. We asked patients at their last visit: "If you lost your hearing device, how much would you be willing to pay to replace it?" Monthly incomes were recorded to adjust for variation in income.

Age, pure tone thresholds, and pure tone average were analyzed for baseline differences using analysis of variance (ANOVA). Dimensional (continuous) data were summarized using mean incremental differences between baseline and 3-month scores. The incremental scores were compared with t-tests for pairwise comparisons and ANOVA for multiple comparisons. Comparisons of dichotomous (frequency) data were analyzed with c^2 tests. Because multiple comparisons were used, we have highlighted only results that were statistically significant at an a=.01 level. Statistical analyses were performed with SAS software (SAS Institute, Cary, North Carolina, version 6.12).

No statistically significant differences for age or degree of hearing loss at baseline were noted between arms. To correct for minor variations in baseline scores for some outcome variables, mean *incremental* results are reported (scores at baseline subtracted from those at 3 months).

RESULTS

The type of hearing amplification strongly influenced Hearing Handicap Inventory for the (HHIE) scores. The overall HHIE score, which ranged from 0 to 100, did not change significantly in either the control arm. However, it improved 17 points in patients using the standard aid (P<.01), and over 31 points in patients with the programmable aid (P<.01). Similar trends were observed for both the social and emotional subscales. Clear differences were apparent from the clinimetric analysis of open-ended diary comments as well. In general, positive (favorable) comments occurred more often as the technology became more advanced, and negative (unfavorable) comments occurred less often.

Self-reported adherence to use of the hearing devices also varied significantly between arms. Patients used the programmable hearing aid an average of 8.8 hours/day, and the standard aid 6.9 hours/day.

When patients were asked how much they would be willing to pay to have their amplification devices replaced if they lost them, patients using the ALD offered a mean of $40, or 1% of their monthly income, to replace the device. Patients using standard aids said that they would be willing to pay $800, or approximately 29% of their monthly income. Patients who received the programmable aids indicated they would pay over $2,240, or approximately 78% of their monthly income.

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CONCLUSIONS

In this randomized trial comparing the effectiveness of three amplification strategies against a control arm, clear treatment effects were apparent. Both hearing aids were superior to an assistive listening device and the absence of amplification in all measures of outcome, including hearing-related quality of life, self-reported communication ability, adherence, and willingness-to-pay. These observations confirm the results of prior randomized trials comparing the use of a hearing aid against no intervention.

Of more interest is the finding that there are differential treatment effects between hearing aids. The programmable hearing aid with a directional microphone performed better than the standard non-programmable aid did. Results were particularly convincing with respect to quality of life and willingness-to-pay data. Ultimately, definitive randomized trials and more advanced technology assessment techniques will be needed to identify the hearing aid features that are truly responsible for improved effectiveness.

REFERENCES

Feinstein AR (1987). Clinimetrics. New Haven, Connecticut: Yale University Press.

Jerger J, Chmiel R, Florin E, Pirozzolo F, & Wilson N (1996). Comparison of conventional amplification and an assistive listening device in elderly persons. Ear Hear, 17(6), 490-504.

Ventry IM, & Weinstein BE (1982). The hearing handicap inventory for the elderly: a new tool. Ear Hear, 3(3), 128-34.

Paper submitted for publication. Study supported by Dr. Yueh's Career Development Award.

Abstracts of Recently Published Articles by VA Investigators

Trends in lower limb amputation in the Veterans Health Administration, 1989-1998. Mayfield JA, Reiber GE, Maynard C, Czerniecki JM, Caps MT, Sangeorzan BJ

Objective: To assess trends in lower limb amputation performed in Veterans Health Administration (VHA) facilities.

Methods: All lower limb amputations recorded in the Patient Treatment File for 1989-1998 were analyzed using the hospital discharge as the unit of analysis. Age-specific rates were calculated using the VHA user-population as the denominator. Frequency tables and linear, logistic, and Poisson regression were used respectively to assess trends in amputation numbers, reoperation rates, and age-specific amputation rates.

Results: Between 1989-1998, there were 60,324 discharges with amputation in VHA facilities. Over 99.9% of these were in men and constitute 10 percent of all U.S. male amputations. The major indications were diabetes (62.9%) and peripheral vascular disease alone (23.6%). The age-specific rates of major amputation in the VHA are higher than U.S. rates of major amputation. VHA rates of major and minor amputation declined an average of 5% each year, while the number of diabetes-associated amputations remained the same.

Conclusion: The number and age-specific rates of amputations decreased over 10 years despite an increase in the number of veterans using VHA care. *J Rehabil Res Dev* 2000 Jan-Feb; 37(1): 23-30

Outcomes of coronary angioplasty procedures performed in rural hospitals. Maynard C, Every NR, Chapko MK, Ritchie JL

Purpose: To determine how many rural hospitals in the United States performed coronary angioplasty; to compare patient outcomes in rural and urban hospitals; and to assess whether outcomes were better in rural hospitals in which more procedures were performed.

Subjects and Methods: In 1996, among patients 65 years of age and older, 201,869 coronary angioplasties were performed in 996 hospitals that were included in the Medicare Provider Analysis and Review files. Geographic location was defined as rural or urban, according to U.S. Census Bureau criteria. Outcome variables were in-hospital death and coronary artery bypass surgery performed during the same admission. Hospital volumes were categorized as low (< or = 100 cases or fewer per year), medium (101 to 200 cases per year), or high (> 200 cases per year).

Results: Fifty-one rural hospitals accounted for 4% of all angioplasties performed. After angioplasty, in-hospital mortality was greater in rural hospitals (8.1% versus 6.4%, P = 0.001) among patients with acute myocardial infarction, but was not different for patients without infarction (1.4% versus 1.3%, P = 0.41). Coronary artery bypass surgery rates during the same admission were similar in rural and urban hospitals. In general, in-hospital mortality and same-admission surgery rates were lower in high-volume centers in both rural and urban areas.

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WHAT'S HAPPENING AT THE NW HSR&D CENTER OF EXCELLENCE

Personnel Changes in HSR&D

Some staffing changes have occurred in the Seattle-Portland HSR&D Center of Excellence this year. A temporary change is the departure in July of Stephan Fihn, COE Director, for a year-long sabbatical to the University of Leiden, Netherlands. Dr. Susan Hedrick is Acting Director. Anyone wishing to reach Dr. Fihn while he is in Leiden can e-mail him at the following address: sfihn@u.washington.edu.

Also in July, Dr. Nathan Every resigned as an Investigator to take a position as partner in a Seattle-based, biotechnology venture capital fund.

HSR&D welcomes Dr. Marcia Burman as an investigator. After being an HSR&D fellow for the past three years, Marcia received a VA HSR&D Career Development Award. See page 6 for details.

Dr. Donald Martin, Mathematical Statistician is retiring from government service at the end of September after six years with HSR&D. Don retired from the Department of Biostatistics, University of Washington in 1996 after 24 years teaching and working mostly in research doing statistical design and analysis of scientific studies.

Between the Seattle COE and Portland affiliate, there are 13 new fellows in our various fellowship programs for 2000-2001:

HSR&D Predoc PhD trainees	Joseph Dettori Katrina Moore
HSR&D Postdoc PhD fellows	Jane Tornatore
RWJ Clinical Scholars fellows	Christopher Flowers Gary Winzelberg
HSR&D Postdoc MD fellows	Kimberley Marquis Dariush Mozaffarian
Ambulatory Care MD fellows	Minnie Huang Christopher Bryson George Ioannou
Medical Informatics fellows	Peter Embi Jane Donat
Women's Health MD fellows	Lina Takano

Annual Report Template (ART) Training

The NW HSR&D Center of Excellence held a two-day training seminar the end of August at the Seattle VA Puget Sound Health Care System on implementation of an updated Annual Report Template (ART), a program created in MS ACCESS. ART describes resources, activities, and accomplishments during the fiscal year and plans for the next fiscal year for each HSR&D Center of Excellence and Resource Center. Output from the ART is also used to create the Progress Reports Book, generate Research and Development Information System (RDIS) forms, and provide a data source for site personnel contact and project information.

Jean Sullivan, Project Director along with Jane Summerfield, Acting Administrative Officer; Genevieve Herreria, Program Assistant; and Nancyjean Tripp, Program Secretary successfully brought together 30 people from 15 Center's of Excellence along with MDRC and VA Headquarters staff to learn how ART has expanded and improved and how this valuable resource can be used.

The Center's of Excellence Annual Reports are due by October 30. If there are any questions about this new database, please contact Jean Sullivan, Seattle HSR&D, 206.768.5337 or e-mail jean.sullivan@med.va.gov.

Conference attendees enjoyed a Northwest-style salmon cookout at Jean's house, prepared by her husband, Paul Bauck.

FELLOWS' PROFILES

Bessie Young, MD

Bessie is currently a third year research fellow in HSR&D. Originally trained in Nephrology at the University of Washington, Bessie's primary interest is in the assessment and treatment of diabetic nephropathy, improving quality of care, and improving access to care for this group of patients. She has also been studying the morbidity and mortality associated with diabetic nephropathy in the national veteran population.

Being a native Washingtonian, Bessie went to college at Pacific Lutheran University in Tacoma, Washington. She completed medical school training, an Internal Medicine residency, and a Nephrology fellowship at the University of Washington in Seattle.

Bessie enjoys traveling and hiking and recently returned from a hiking trip to the Grand Canyon, the Mesa Verde plateau in Colorado and the Chaco Culture National Monument in New Mexico. She also enjoys skiing, singing in a choir, skating, reading and driving fast cars. She is married to Marco Mielcarek, an Oncology fellow from Berlin, Germany.

Cornelia Dahm, MD

Cornelia is in the second-year of her HSR&D MD postdoctoral fellowship. She grew up on a farm in the South of Germany and went to Medical School at Ruprecht-Karls-Universität in Heidelberg. While on a scholarship at the Medical College of Ohio Cornelia learned to appreciate and enjoy the medical training in the U.S. After finishing Medical School and her internship in Germany she returned to the U.S. She did a residency in internal medicine at the University of Minnesota and moved to Seattle for a pulmonary and critical care fellowship at the University of Washington.

Her research interests initially included laboratory techniques for the detection of Herpes Simplex Virus. During her training in the U.S., she worked on the fibroproliferative response of pulmonary fibroblasts. Realizing the importance of continuing clinical studies to guide patient care, she decided to take classes at the School of Public Health, University of Washington. Her current projects are focused on the use of large databases and include studies of satisfaction in COPD patients and risk factors for osteoporosis.

Cornelia thinks that the Pacific Northwest is one of the most beautiful places she's ever lived. She loves to be outdoors and goes hiking, running, biking, kayaking and skiing. She also enjoys cooking and baking - especially with a group of her friends!

David Au, MD

David is currently a third year HSR&D research fellow. Having trained clinically in Pulmonary and Critical Care Medicine at the University of Washington, David's primary research interest concern improving quality of care for patients with Chronic Obstructive Pulmonary Disease. In particular, he has been examining the risk of cardiac complications associated with inhaled beta-agonist therapy. David also has interests in the assessment of health status, including health-related quality of life among COPD patients.

Before coming to Seattle for sub-specialty and research training, David attended the University of Chicago Pritzker School of Medicine, completed residency training in internal medicine at Case-Western Reserve University Hospitals of Cleveland.

David's principal hobby is fly-fishing. He enjoys spending time fishing in and around the Seattle area. He also enjoys many other outdoor activities in the area including hiking, white-water rafting, photography, skiing and scuba diving.

MARCIA L. BURMAN, MD, MPH

Dr. Burman has recently begun work on an HSR&D Career Development Award that will provide three years of protected research time. She came to the VA Puget Sound Health Care System in 1997 for HSR&D fellowship training after completing her Internal Medicine Training at Barnes-Jewish Hospital – Washington University in Saint Louis.

Dr. Burman's research interest is in the implementation and effectiveness of clinical practice guidelines. Her fellowship work included studies to evaluate the effect of false-positive mammograms on repeat breast cancer screening as well as factors associated with primary care provider's screening for and advising against hazardous alcohol use. The focus of her work for her Career Development Award will be to develop sensitive computerized measures of compliance with chronic disease management guidelines and evaluate patient outcomes by level of compliance. She also hopes to develop criteria for choosing the most effective guideline implementation strategy based on individual guideline characteristics.

In addition to her research, Dr. Burman provides medical care to veterans in the General Internal Medicine Clinic and provides training and supervision of Internal Medicine Residents both in the clinic and on the hospital wards.

Dr. Burman's husband, Dr. Michael Kalnoski who is originally from the Puget Sound region, began his Pathology Residency at the University of Washington three years ago when they moved back to the Seattle area for Dr. Burman to began her VA fellowship. Dr. Burman, her husband and seven year old son, Max, have been enjoying the return to family and friends, and many of the recreational opportunities in the Northwest. They are avid skiers and campers, and Dr. Burman is fulfilling a life-long dream this summer by learning to sail.

Northwest HSR&D Center of Excellence

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HSR&D Newsletter

The Northwest HSR&D COE Newsletter is published twice yearly. Contributions for publication should be sent to:

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HSR&D Deadlines

Local deadline for proposal review is two weeks prior to Research Review Committee meeting and two months prior to VAHQ deadline. Review Committee meets on 1st Friday of each month.

VAHQ Deadlines

Letters of Intent (LOI): Accepted any time, reviewed monthly. Guidelines in Instructions for Submitting a Letter of Intent, January, 2000.

Investigator-Initiated Research Proposals (IIR): Due May 1 and November 1. An approved LOI is required prior to submission. Guidelines in Instructions for Preparing Investigator-Initiated Research Proposals, October, 1997.

Nursing Research Initiatives (NRI): Due December 1 and June 1. An approved LOI is required prior to submission. Guidelines in Instructions for Preparing Investigator-Initiated Research Proposals, October, 1997.

Research Career Scientist: March 1 and September 1. Guidelines in RCS Directive VHA Notice 98-02.

Career Development: Due February 15 and August 15. Must have approved LOI prior to submission; due November 1 and May 1. Guidelines in CDA Directive VHA 1201.8.

For current guidelines and forms, please refer to www.va.gov/resdev

Phone Listings for HSR&D Service, VA Headquarters

Director - John Demakis, MD	(202)	273-8287
Deputy Director - Shirley Meehan, MBA, PhD	(202)	273-8287
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Career Development Program Manager - L. Robert Small, Jr.	(202)	273-8256
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Project Updates

The Chronic Disease Score in a VA Population

Anne E.B. Sales, PhD, Chuan-Fen Liu, PhD, and Kevin Sloan, MD

The study seeks to provide a low-cost, practical and clinically relevant pharmacy-based risk adjuster to predict VA health care costs and utilization. This study is to replicate the Chronic Disease Score (CDS) in a VA population, refine it for improved performance in VA, and to compare its performance to that of other leading risk adjustment methods. The results have direct applicability to VA administrators who want to use risk adjustment as an aid in allocating resources between regional networks or facilities, setting capitation rates for private contractors, or comparing outcomes across providers.

This study follows previous research that uses the CDS, a measure of co-morbidity and relative disease severity based on pharmacy utilization. The CDS predicts health care costs using a regression equation with the following independent variables: age, sex and the chronic condition classes in which drug fills are observed. Previous versions of the CDS have proven valid and reliable predictors of future health care costs and appear to perform about as well as more widely used risk adjustment methods.

Our primary research question is whether a VA-modified version of the CDS has at least as high predictive validity than three other leading risk adjustment methods: (1) the commercial version of the CDS (GH CDS), (2) Ambulatory Care Groups (ACGs), and (3) Hierarchical Coexisting Conditions (HCCs). In secondary analyses we will also explore the extent to which combining risk adjusters (VA CDS + ACGs and VA CDS + HCCs) further improves predictive validity.

Clinical Trial of Footwear in Patients with Diabetes

Gayle E. Reiber MPH, PhD and Douglas G. Smith, MD

In the Clinical Trial of Footwear in Patients with Diabetes, Drs. Reiber and Smith are 1) determining the extent to which study shoes and study insoles will reduce the incidence of reulceration in diabetic individuals with a prior history of foot ulcer, and 2) estimating costs of ulcer prevention using these strategies.

400 patients from the VA Puget Sound Health Care System and Group Health Cooperative were randomly assigned to one of three study arms: Arm 1 (n=121) = study shoes and study cork insoles; Arm 2 (n=119) = study shoes and study polyurethane insoles and Arm 3 (n=160) = controls who wear their own footwear. Patients in Arm 1 and 2 received a pair of formal, leisure and athletic shoes built to their specifications at cost by Cole-Haan for men and Lowell Shoe for women. Patients in Arm 1 received customized study insoles fabricated by our study team with each pair of shoes. Patients in Arm 2 received study polyurethane insoles for each pair of study shoes. All study patients received a pair of house slippers.

Footwear worn by all study patients has been closely monitored throughout the trial. Footwear compliance for patients in the intervention arms at one year was 85.8% for Arm 1 and 90.2% for Arm 2.

Patients are being followed for two years to determine the incidence of foot reulceration as the main outcome measure. Falls and health care costs and cost of footwear are being examined in the trial. The clinical trial findings will be released at the 61st Scientific Session of the American Diabetes Association in Philadelphia, PA in June 2001. Information on the trial results and recommendations will also be provided to VA RR&D, HSR&D, surgical, family practice, podiatric, and pedorthic professional groups by mid-2001.

Abstracts of Recently Published Articles by Investigators

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Conclusions: Although in-hospital mortality after angioplasty for acute myocardial infarction was worse in low- and medium-volume rural centers, overall outcomes in rural and urban hospitals were similar.

Am J Med 2000 Jun 15;108(9): 710-3